IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC. Defendant.	[redacted] C.A. No. 21-691-GBW
JAZZ PHARMACEUTICALS, INC., *et al.*, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC. Defendant.	[redacted] C.A. No. 21-1138-GBW
JAZZ PHARMACEUTICALS, INC., *et al.*, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC. Defendant.	[redacted] C.A. No. 21-1594-GBW

RESPONSIVE LETTER TO THE HONORABLE GREGORY B. WILLIAMS IN OPPOSITION TO PLAINTIFF'S MOTION TO COMPEL DAMAGES DISCOVERY

Dear Judge Williams:

Defendant Avadel CNS Pharmaceuticals, LLC ("Avadel") respectfully opposes Jazz's motion to compel discovery related to damages in this case. D.I. 194. As a result of Jazz's ongoing efforts, including the improper listing of the '963 patent in the Orange Book, Avadel has been unable to launch its once-nightly narcolepsy treatment, LUMRYZ™. Unless that patent is delisted, it will continue to block FDA approval of LUMRYZ until June 2023. Until and unless Avadel is able to commercially market LUMRYZ, Jazz does not have a statutory claim for damages, and the discovery Jazz seeks is therefore not relevant to the claim or defense of any party. Indeed, while Jazz's letter repeatedly refers to the appearance of the word "damages" in its Complaint, that request is explicitly predicated on the commercial sale of LUMRYZ. Thus, damages-related discovery is not warranted, and Jazz's motion to compel should be denied.

A. Background

Jazz initiated this series of actions under the Hatch-Waxman Act on May 12, 2021, alleging patent infringement under 35 U.S.C. § 271(e)(2)(A)[1] based on Avadel's filing of a New Drug Application ("NDA") for its once-nightly narcolepsy treatment, LUMRYZ. In its prayer for relief, Jazz acknowledged that Avadel had not yet engaged in acts that would form the basis for a damages claim, seeking damages only "***[i]f*** Avadel engages in the commercial manufacture, use, sale, or offer for sale, or importation into the United States" of Avadel's NDA Product prior to the expiration of the patents-in-suit.[2] D.I. 1 at 23 (emphasis added unless otherwise noted). Jazz's conditional request thus tracks the express language of the Hatch-Waxman Act, which provides for damages "***only if*** there has been commercial manufacture, use, offer to sell, or sale within the United States." 35 U.S.C. § 271(e)(4)(C).

Since that time, Jazz has worked assiduously to prevent LUMRYZ from entering the market, including through maintaining the improper listing of the '963 patent in the Orange Book and seeking to delay resolution of Avadel's Rule 12(c) motion aimed at delisting that patent. Jazz has also suggested that other regulatory exclusivities may prevent Avadel's entry to the market until 2027. D.I. 165 at 7, n. 3. Despite taking the position that Avadel will not be able to launch LUMRYZ until well into 2023, if not later, Jazz did not raise any issues related to damages discovery when the parties negotiated a schedule in this case. Instead of proposing a solution to an issue it should have foreseen at that time, Jazz agreed to a schedule with a fact discovery cutoff of October 21, 2022. D.I. 71 at 2.

[1] Jazz also alleged that Avadel will infringe under 35 U.S.C. §§ 271(a), (b), and (c) upon approval of its NDA. However, because Avadel's NDA is not yet approved, Avadel has not engaged in any activities that would constitute infringement under §§ 271(a)-(c).

[2] Jazz also sought damages "[t]o the extent that Avadel has committed any acts with respect to the composition or methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1)," *i.e.*, to the extent Avadel failed to comply with the so-called "safe-harbor provision" that exempts from infringement liability acts done for uses reasonably related to the development and submission of information under certain Federal Laws, such as the Hatch-Waxman Act. D.I. 1 at 22. Jazz has not contended that Avadel has engaged in any such activities or that they would form the basis of a damages claim.

Jazz served the RFPs that are the subject of the instant motion on June 17, 2022, three months after the deadline for the substantial completion of document production. D.I. 71. In Avadel's responses to those RFPs, Avadel objected on the basis that they are not relevant or proportional to the needs of the case. D.I. 194, Ex. B. On the parties' September 15, 2022 meet and confer and in related correspondence, Jazz confirmed that its requests are solely relevant to a potential damages claim. *See* D.I. 194, Ex. C. In response, Avadel explained that in the absence of any infringing sales, Jazz lacks any claim for damages, and damages are therefore not the proper subject of discovery. D.I. 194, Ex. D.

B. Argument: Jazz Is Not Entitled To Damages-Related Discovery

Pursuant to FED. R. CIV. P. 26(b)(1), discovery is limited to information "that is relevant to any party's claim or defense and proportional to the needs of the case." Where infringement is asserted under § 271(e)(2), "damages or other monetary relief may be awarded against an infringer ***only if*** there has been commercial manufacture, use, offer to sell, or sale within the United States or import into the United States of an approved drug." 35 U.S.C. § 271(e)(4)(C). That is, if the alleged act of infringement is the filing of an NDA per § 271(e)(2)(A), as it is here, damages cannot be awarded until there is a sale or other commercial use of the accused product. Thus, until and unless Avadel sells LUMRYZ, Jazz has no "claim" for damages. *See, e.g., FTC v. Actavis, Inc.*, 570 U.S. 136, 147 (2013) ("The FTC alleges that in substance, the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market, even though the defendants did not have any claim that the plaintiff was liable to them for damages."); *MedImmune, Inc. v. Genentech, Inc.*, 535 F. Supp. 2d 1020, 1031 (C.D. Cal., 2008) ("Filing an ANDA filing represents an artificial, statutory act of infringement under 35 U.S.C.§ 271(e)(2)," and thus "patentees in Hatch-Waxman cases have no claim for damages"); Ex. A (*"Actavis" Case Analysis*) ("These types of agreements are labeled 'reverse payment' settlements because they require that the patent holder pay the alleged infringer despite the fact that the alleged infringer has no claim for damages in the underlying dispute."). Jazz has acknowledged as much by pleading that it would seek damages only "[t]o the extent Avadel has committed any acts with respect to the compositions or methods claims in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)" or "engages in the commercial manufacture, use, sale, or offer for sale, or importation" of LUMRYZ. D.I. 1 at 22-23. Jazz's letter brief concedes that Avadel has not committed any such "acts." D.I. 194 at 1 (conceding that "there may not be any actual damages accruing currently since Avadel's product is not yet on the market"). Axiomatically, given the circumstances, the damages related discovery Jazz seeks is not "relevant to any party's claim or defense."

Contrary to what Jazz suggests, the information Jazz seeks is not "routinely considered discoverable" in Hatch-Waxman cases where infringement is asserted under § 271(e)(1). D.I. 194 at 3. Damages discovery is not the norm in Hatch-Waxman cases for the same reason damages are not relevant here: no product has been sold. *See, e.g., MedImmune*, 535 F. Supp. 2d at 1031. Moreover, the three cases Jazz cites in support of its assertion that the requested information is routinely discoverable are all non-Hatch Waxman patent litigation cases. None were brought under § 271(e)(2). *See* D.I. 194 at 3 (citing cases).

Avadel presently is barred from obtaining final approval from FDA and launching LUMRYZ because Avadel was required to submit a certification to Jazz's improperly-listed '963 patent. This certification resulted in a stay of the regulatory approval process of Avadel's NDA

for LUMRYZ when Jazz filed a lawsuit for the sole purpose of triggering that stay and keeping Avadel's NDA product off of the market. Given the circumstances, there have been no sales of Avadel's product, Jazz has no claim for damages, and the discovery Jazz seeks is not relevant to the claim or defense of any party. Thus, Jazz's motion should be denied. However, even if this Court is inclined to allow Jazz to seek damages discovery, it should not grant Jazz the relief it requests. Jazz's proposals for accommodating damages discovery are inefficient and unworkable.

First, Jazz contends that it should be granted damages-related discovery now, and later be permitted to "supplement" that discovery if and when Avadel launches its NDA product. D.I. 194 at 3. This proposal makes little sense. The majority of relevant information to a damages case—including Avadel's actual sales, revenue, profits, costs, and market share—will not be available until ***after*** Avadel launches its product. Jazz's suggestion that damages discovery can be later "supplemented" treats this case like an ordinary patent case, where supplemental damages discovery merely involves updating the values for preexisting damages calculations. Here, the "supplemental damages-related discovery" Jazz asserts that it is entitled to would entail re-opening fact and expert discovery to engage in a wholesale revision of Jazz's damages theory based on Avadel's ***actual*** sales and the impact of LUMRYZ on the market. This proposal is inefficient and impractical.

Jazz also suggests that discovery may be bifurcated into a liability component and a damages component. D.I. 194 at 3, n. 3. This suggestion is equally impractical. Bifurcated discovery could result in two trials—a trial on liability and, if Jazz were successful, a second trial on damages. In addition, there is another action, the related trade-secret case, pending in this district. C.A. No. 22-487. That case relates to Jazz's improper use of Avadel's confidential information regarding Avadel's proprietary once-nightly oxybate technology, [redacted] C.A. No. 22-487, D.I. 2. In short, Jazz's suggestion is that the Court potentially hold three separate trials on substantially overlapping issues, which is an inefficient use of the Court's scarce resources and three separate juror pools.

If the Court believes that damages discovery is appropriate in this case, the most efficient and appropriate solution is to grant Avadel's request to consolidate this case with the co-pending trade secret case. C.A. No. 22-487, D.I. 12. This would extend fact discovery until Avadel can launch LUMRYZ, obviate the need for bifurcation or successive rounds of discovery and expert reports, and result in one trial rather than the multiple trials Jazz proposes. Moreover, consolidation would reduce the need for duplicative discovery, as the trade secret case centers around [redacted] which overlaps substantially with Avadel's claims and defenses in this case.

Jazz is not entitled to damages-related discovery because it has no active claim for damages until Avadel launches a product—which Avadel is currently statutorily prevented from doing [redacted] Allowing discovery now would be a waste of time and resources, as would bifurcation. To the extent any damages discovery sought by Jazz is warranted, Avadel respectfully requests that this Court set a schedule that consolidates this case with Avadel's trade secret misappropriation case, and allows adequate time for damages-related discovery.

Respectfully submitted,

/s/ Daniel M. Silver

Daniel M. Silver (#4758)

cc: Counsel of Record (via E-Mail)

EXHIBIT A

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"Actavis" Case Analysis: Supreme Court Says Certain Patent Infringement Settlements Could Violate Antitrust Laws

June 27, 2013

F. Matthew Ralph , Jaime Stilson

On June 17, 2013, the Supreme Court issued its much-anticipated ruling in *Federal Trade Commission v. Actavis, Inc. et al.* (No. 12-416), holding that reverse settlement payments (also known as "pay for delay" settlements) between branded and generic pharmaceutical companies in patent infringement litigation are subject to "rule of reason" analysis. The case represents a victory for the FTC, whose bid to bring "pay for delay" settlements under antitrust scrutiny was rejected by the district court and Eleventh Circuit on the grounds that any anticompetitive effects of the settlement at issue fell within the exclusionary scope of the patent and were therefore immune from antitrust scrutiny.

The case arose from Solvay Pharmaceutical's patent on its approved brand-name drug AndroGel. Several pharmaceutical companies, including Actavis and Paddock, filed Federal Drug Adminsitration (FDA) applications for generic drugs modeled on AndroGel. They claimed, pursuant to a provision under the Hatch-Waxman Act ("paragraph IV"), that Solvay's patent was invalid and that their drugs did not infringe it. The FDA approved the generics. Solvay nevertheless sued Actavis, Paddock and Par, for patent infringement pursuant to Hatch-Waxman Act procedures. The parties entered into a settlement whereby Solvay (the patent holder) agreed to pay millions of dollars to Actavis and Paddock (the alleged infringers) in exchange for Actavis' and Paddock's agreements (1) not to bring their generic drugs to market for a set number of years within the scope of the challenged patent's term and (2) to promote AndroGel to doctors during the settlement period. These types of agreements are labeled "reverse payment" settlements because they require that the patent holder pay the alleged infringer despite the fact that the alleged infringer has no claim for damages in the underlying dispute. Such agreements are also known as "pay for delay" settlements because the alleged infringer agrees to postpone entry into the market during the settlement period.

The FTC brought suit challenging the settlements under Section 5 of the FTC Act, claiming that the parties unlawfully agreed to delay competition in order to share in Solvay's alleged monopoly profits. The district court dismissed the case, and the Eleventh Circuit affirmed, concluding that the settlement was immune from antitrust scrutiny because any anti-competitive effects of the settlement fell within the exclusionary scope of the patent.

In a 5-3 ruling, the Supreme Court reversed. The majority concluded that patent policy does not completely displace antitrust policy in the context of reverse settlements and that the Hatch-Waxman Act's goal to facilitate entry by generic drug manufacturers supports the need for antitrust scrutiny of such settlements. Op. at 12-14. The majority further concluded that the policy favoring settlement of disputes, particularly in complex patent litigation, was outweighed by competing antitrust considerations in the reverse settlement context. "[A] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle disputes without the use of reverse payments." Op. at 19-20. The three-justice dissent would have affirmed on the ground that antitrust laws are not applicable to settlements that fall within the scope of the patent.

It remains unclear whether and to what extent *Actavis* will deter reverse settlements, stimulate private antitrust litigation related to them, or influence antitrust analysis of other conduct where patent and antitrust law overlap (e.g., standard-essential patents). At minimum, *Actavis* signals that patent holders can no longer rely exclusively on "scope of the patent" arguments to immunize reverse or pay-for-delay settlements from antitrust analysis. As a result, patent holders likely will be unable to fend off suits challenging such settlements by motions to dismiss. Companies considering such settlements will need to evaluate, in particular, what procompetitive justifications support the terms of the settlement. The majority offered little guidance regarding which procompetitive justifications might pass muster under a rule-of-reason analysis beyond litigation costs and services performed by the generics, and this topic seems ripe for future litigation. A copy of the opinion is available at the Supreme Court's website.

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that true and correct copies of the foregoing document were caused to be served on October 18, 2022 on the following counsel in the manner indicated below.

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Dated: October 18, 2022

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